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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,794	12/27/2001	Yasuo Komatsu	033808/0272544	7169

7590

02/25/2004

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EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.A.M.

Office Action Summary

Application No.

10/032,794

Applicant(s)

KOMATSU ET AL.

Examiner

Jane Zara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 11-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11-24-03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: sequence compliance.

DETAILED ACTION

This Office action is in response to the communication filed 11-24-03.

Claims 1-21 are pending in the instant application.

Election/Restrictions

Claims 7, 11-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11-24-03.

Applicant's election without traverse of Group I, claims 1-6, 8-10, in Paper No. 11-24-03 is acknowledged.

Information Disclosure Statement

The abstracts only of the Japanese documents 8-131163, 6-181758 and 10-215876 have been considered by the examiner in the information disclosure statement filed 11-24-04, since the translations provided only concerned the abstracts of these documents.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or

Amino Acid Sequence Disclosures. Please provide appropriate accompanying SEQ ID Nos. for the nucleotide sequences listed in the specification, figures or figure descriptions, and claims (e.g. see figures 1-4 and structures I, II and III of the claims). Please see accompanying notice to comply.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 2, it is unclear which portion of the ribozyme must hybridize with the oligonucleotide (e.g. is this an allosteric or substrate binding phenomenon being claimed?). It is also unclear under what conditions hybridization is required to take place for the activation to occur. Therefore, the metes and bounds of the claimed invention cannot be determined. Appropriate clarification is requested.

In claim 3, line 2, it is unclear whether the target nucleotide sequence referred to is the cleavage site sequence required for the ribozyme cleavage, or a larger target sequence of an intended target gene. Appropriate clarification is requested.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to hairpin ribozymes that are activated by changes in their stem-loop structure upon hybridization with an oligonucleotide, and optionally wherein the oligonucleotide is part of a target nucleotide sequence, and wherein the hairpins optionally exhibit a complex structure shown in general formulae I or II. The specification and claims do not indicate what distinguishing attributes are concisely shared by the members of the genus comprising these hairpin ribozymes activated by changes in their stem-loop structure upon hybridization with an oligonucleotide. The scope of the claims includes numerous structural variants and the genus is highly variant because a significant number of structural differences between genus members (e.g a myriad of nucleotide sequences and lengths; a myriad of conditions under which hybridization is achieved) is permitted. Concise structural features or characteristics that could distinguish compounds in the genus from others within this broad genus are missing from the disclosure. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species (e.g. polynucleotide sequences 1 and 2

have been illustrated in the instant disclosure) to adequately describe the very broad genus claimed. Thus Applicant was not in possession of the claimed genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6 are rejected under 35 U.S.C. 102(b) as being anticipated by
Komatsu et al.

Komatsu et al (J. Mol. Biol. 252 :296-304, 1995) teach hairpin ribozymes that are activated by changes in their stem-loop three dimensional structures upon hybridization with an oligonucleotide, which oligonucleotide is between 3-23 base pairs, and which oligonucleotide is part of a target nucleotide sequence, whereby trans-cleavage of target substrates occur (See entire document, especially the abstract; fig. 1 on page 297, figure 3 on page 298; text on 299-300; fig. 6 on page 301; text on page 302).

Claims 1-4, 6, and 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Hampel et al.

Hampel et al (USPN 6,221,661, Apr.24-01) teach host cells comprising recombinant vectors or DNA encoding hairpin ribozymes that are activated by changes

in their stem-loop three dimensional structures upon hybridization with an oligonucleotide, which oligonucleotide is between 3-23 base pairs, and which oligonucleotide is optionally part of a target nucleotide sequence, whereby trans-cleavage or cis-cleavage of target substrates occur (see entire document, especially the abstract; col. 2, line 55-col. 4, line 4; col. 13, line 18-col. 20, line 40; col. 21, lines 26-36; col. 23, lines 47-67; col. 25, lines 35-45).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the

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status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'm Shukla', written over a horizontal line.

**RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER**

JZ

2-19-04